

RECEIVED
CENTRAL FAX CENTER
NOV 14 2006

REMARKS

Applicants have carefully reviewed the Office Action dated August 14, 2006. Applicants have amended Claims 21, 25, and 29-36 to more clearly point out the present inventive concept. Reconsideration and favorable action is respectfully requested.

Claims 31 through 36 are pending in this Application.

Claims 21, 25, and 29-36 have been amended.

Claim 37 has been newly cancelled.

REGARDING THE § 103 REJECTION

Claims 21-23, 26-34 and 36 were rejected under 35 U.S.C. § 103(a) for being rendered obvious by *Anderson et al.* (U.S. Patent No. 5,922,591). Applicants would agree with the Examiner that *Anderson* teaches a cartridge and an analytical instrument. Applicants would also agree that *Anderson* expressly teaches that a reaction chamber portion can be mated with a reusable base unit which provides some elements. Applicants would also agree with the Examiner that *Anderson* teaches various fluid chamber dimensions. Regardless, applicant respectfully points out that *Anderson*, in column 21 beginning around line 59, discusses input and output ports to a reaction chamber. *Anderson* discusses "one or more fluid channels which connect the reaction chamber to an inlet/outlet port for the overall device, additional reaction chambers, storage chambers or one or more analytical chambers." *Anderson* in column 22 goes on to discuss at line 49 that multiple chambers are connected in series and that various operations are carried out wherein "each of [the] reaction chambers is assigned one or more different functions." In column 23 of *Anderson*, starting at line 22, *Anderson* discusses an amplification chamber and how amplification agents may be introduced to the reaction chamber 210. In column 24, starting at line 9, *Anderson* goes on to discuss Figs. 4A through 4C, which illustrate a micro-capillary electrophoresis device. The micro-capillary electrophoresis device discussed in *Anderson* comprises a sample reservoir 402 which "may be a separate chamber, or may be

AMENDMENT AND RESPONSE

SN: 09/982,307

Atty. Dkt. No. 10003714-1

AGIL-27,470

Page 8 of 13

BEST AVAILABLE COPY

merely a portion of the fluid channel leading to a previous reaction chamber." By *'separate'*, Anderson means a separate chamber within the same cartridge. Applicant points out that there is no discussion or teaching in *Anderson* indicating that this electrophoresis device could be part of a detachable companion cartridge. Applicant respectfully submits that such an electrophoresis device would not operate or be functional properly if it was divided into two detachable cartridges due to the non-uniformity of inter-cartridge fluid connections and the minute amount of fluid flow produced by an electrophoresis process. Furthermore, there is no discussion in this portion of *Anderson* or any other portion of *Anderson* about calibration of an active element that is either a reusable active element, a regeneratable active element, or a single use active element. Applicant further submits that *Anderson* does not teach, allude to, or render obvious "a waste fluid retrieval system for retrieving waste fluid directly from said associated sensing cartridge body via a second tube in said companion body fluid analyzing cartridge after said calibration fluid is provided to said sensing cartridge via said first tube." *Anderson* provides no discussion teaching of using a calibration fluid, originating from a fluid reservoir in a companion body fluid cartridge, for the calibration of a sensing cartridge body and then providing the calibration fluid back to a detachable companion body fluid analyzing cartridge.

As such, independent Claim 21 has been amended to recite, among other things, "A companion body fluid analyzing cartridge comprising . . . a first port . . . being aligned with a fluid input port on said associated sensing cartridge body; a first tube connected to said first port; a fluid reservoir . . . connected to said first tube; and a waste retrieval system for retrieving waste fluid directly from said associated cartridge body via a second tube in said companion body fluid analyzing cartridge after said calibration fluid is provided to said cartridge body via said first tube." Applicant respectfully submits that *Anderson et al.* does not teach, allude to, or render obvious a waste fluid retrieval system on a detachable companion body fluid analyzing cartridge for "retrieving waste fluid directly from said associated sensing cartridge body" as recited. As such, Applicants respectfully request that the § 103 rejection be withdrawn and submits that Claim 21 is ready for allowance.

AMENDMENT AND RESPONSE

SN: 09/982,307

Atty. Dkt. No. 10003714-1

AGIL-27,470

Page 9 of 13

BEST AVAILABLE COPY

Claims 22 and 23 are each dependent upon Claim 21 and are therefore not rendered obvious for at least the same reasons as discussed above with respect to Claim 21. Applicant also respectfully points out that claim 22 further recites that the "companion cartridge [having the waste fluid retrieval system] detachably connects with said associated sensing cartridge body by at least one of a fluid interface, a mechanical interface, and an electrical interface." Applicant respectfully submits that *Anderson* does not teach, allude to, or render obvious a detachable companion cartridge comprising a waste fluid retrieval system as recited. Applicants respectfully request that the § 103 rejection be withdrawn and submits that Claims 22 and 23 are ready for allowance.

Claims 26 through 33 are each either directly or indirectly dependent upon Claim 21 and are therefore not rendered obvious for at least the same reasons as discussed above with respect to Claim 21. Applicant further notes that Claims 29, 31, 32 and 33 have been amended, not for the purpose of overcoming the rejection, but instead for clarifying the claimed language. Applicant respectfully submits that these claims are not rendered obvious for at least the same reasons as discussed above with respect to Claim 21 and respectfully request that the § 103 rejection be withdrawn.

Claim 34 has been amended to make clear that the claim is directed toward an analytical instrument comprising a companion fluid cartridge, and a sensor cartridge that is detachably connected to the companion fluid cartridge. Applicant respectfully points out that Claim 34 recites that the companion fluid cartridge comprises a reagent storage system connected to a first tube; a waste retrieval system connected to a second tube; and a "fluid reservoir, initially containing a calibration fluid, connected to said first tube and said second tube." Applicants point out that the cited art does not teach, allude to, or render obvious the use of a calibration fluid contained in a fluid reservoir of a companion fluid cartridge.

Claim 34 continues to recite that the sensor cartridge, which is detachably connected to said companion fluid cartridge, "receives said calibration fluid from said companion fluid cartridge via said first tube and provides a waste fluid to said second tube after a calibration

AMENDMENT AND RESPONSE

SN: 09/982,307

Atty. Dkt. No. 10003714-1

AGIL-27,470

Page 10 of 13

BEST AVAILABLE COPY

process is performed, the waste fluid being deposited in said fluid reservoir [of said companion fluid cartridge] via said second tube." Applicants respectfully submit that although *Anderson* teaches a variety of things relative to a diagnostic device, *Anderson* does not teach a calibration fluid contained in a fluid reservoir as claimed in Claim 34. Furthermore, *Anderson* does not teach a sensor cartridge, which is detachably connected to the companion fluid cartridge, that "receives said calibration fluid from said companion fluid cartridge via said first tube and provides a waste fluid to said second tube after a calibration process is performed." Applicants respectfully submit that this intended use does result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from *Anderson*. *Anderson* does not teach, allude to, or render obvious a calibration fluid nor the path of the calibration fluid and resulting waste fluid being from a detachable companion fluid cartridge to a sensor cartridge and back to the same reservoir in the detachable companion fluid cartridge because *Anderson* is limited to teaching a detachable reaction portion (*Anderson* col. 33, ln 31-33) and does not teach the calibration structure or fluid path recited. As such, Applicants respectfully request that the § 103 rejection be withdrawn and submits that Claim 34 is ready for allowance.

Claim 36 has been amended to recite an analytical instrument comprising a companion fluid cartridge and a sensor cartridge. The companion fluid cartridge comprises an assay element preparation system, a waste retrieval system and a "fluid reservoir initially containing only an assay preparation fluid." The sensor cartridge comprises "a regeneratable active element." The sensor cartridge is also "detachably connected to said companion fluid cartridge." Claim 36 further recites that the sensor cartridge is for "receiving said assay preparation fluid from said [fluid reservoir on said companion fluid cartridge and]...said assay preparation fluid being for regenerating said regeneratable active element, said assay preparation fluid turning into a waste fluid after regenerating said regeneratable active element [and wherein] said fluid reservoir being for receiving said waste fluid from said sensor cartridge." Applicants respectfully submit that *Anderson* does not teach, allude to, or render obvious a detachable companion fluid cartridge that has "a fluid reservoir initially containing only an assay preparation fluid" and that also receives a waste fluid from an attached sensor cartridge wherein the waste fluid is the assay preparation

AMENDMENT AND RESPONSE

SN: 09/982,307

Atty. Dkt. No. 10003714-1

AGIL-27,470

Page 11 of 13

fluid that has turned "into waste fluid after regenerating said regeneratable active element." As such Applicants respectfully submit that Claim 36 is not taught, alluded to, or rendered obvious by the cited art.

Claims 24, 25, 35, and 37 were rejected under 35 U.S.C. § 103(a) as being rendered obvious by *Anderson* in view of *Lenier et al.* (U.S. Patent No. 6,037,178).

Applicant respectfully submits that *Lenier* is limited to teaching or render obvious providing a conditioning or calibration fluid from a reservoir in a detachable cartridge to a sensing device and then returning waste fluid to the detachable cartridge into a separate waste fluid receptacle.

With respect to Claims 24 and 25, these claims are dependent upon Claim 21 and are therefore not rendered obvious for at least the same reasons as discussed above with respect to Claim 21 because *Lenier* does not alleviate the inadequacies of the *Anderson* reference. Applicants respectfully request that the § 103 rejection be withdrawn and submits that Claims 24 and 25 are ready for allowance.

Claim 35, as amended, recites a companion fluid cartridge comprising a calibration fluid system, a waste retrieval system and a fluid reservoir "initially containing a calibration fluid." Claim 35 goes on to recite a sensing cartridge that is "detachably connected to said companion fluid cartridge." The "sensing cartridge" receives said calibration fluid from said companion fluid cartridge . . . and calibrates an active area of said sensor cartridge." The sensor cartridge then provides a waste fluid to the companion fluid cartridge "after said calibration process is performed to avoid interference of said waste fluid with a measurement made at said active area of said sensor cartridge, said waste fluid being deposited in said fluid reservoir" of said detachable companion fluid cartridge. Applicants respectfully submit that the amendments to this claim are easily supported in the originally filed Application in paragraphs 22 through 25. Applicants further submit that the combination of *Anderson* and *Lenier* are limited to teaching, alluding to, or rendering obvious providing a conditioning or calibration fluid from a reservoir in a detachable cartridge to a sensing device and then returning waste fluid to the detachable

AMENDMENT AND RESPONSE

SN: 09/982,307

Atty. Dkt. No. 10003714-1

AGIL-27,470

Page 12 of 13

BEST AVAILABLE COPY

cartridge into a separate waste fluid receptacle. There is no suggestion in either reference to reuse the supply reservoir as a waste reservoir. As such, Applicants respectfully submit that Claim 35 is not taught, alluded to or rendered obvious by the cited art and respectfully requests that the § 103 rejection be withdrawn.

Regarding Claim 37, this claim has been cancelled rendering the rejection to this claim moot.

Applicant respectfully submits that the cited references have been overcome because the claims, as amended, recite limitations that result in a structural non-obvious difference from the cited art thereby patentably distinguishing the pending claims over the cited art. Furthermore, the Applicants respectfully submit that the cited art, with respect to the present amended claims, does not provide a proper suggestion or motivation to modify either of the references or to combine the reference teachings to make or use the recited combinations. As such, Applicants respectfully submit that all claims are now ready for allowance.

Applicants have now made an earnest attempt in order to place this case in condition for allowance. For the reasons stated above, Applicants respectfully request full allowance of the claims as amended. Please charge any additional fees or deficiencies in fees or credit any overpayment to Deposit Account No. 20-0780/AGIL-27,470 of HOWISON & ARNOTT, L.L.P.

Respectfully submitted,
HOWISON & ARNOTT, L.L.P.
Attorneys for Applicants


Steven R. Greenfield
Registration No. 38,166

SRG/dd
P.O. Box 741715
Dallas, Texas 75374-1715
Tel: 972-479-0462
Fax: 972-479-0464

AMENDMENT AND RESPONSE
SN: 09/982,307
Att. Dkt. No. 10003714-1
AGIL-27,470

Page 13 of 13